

REMARKS

At the outset, the applicants and the undersigned thank Examiner Minnifield for her time and for her helpful comments during a telephonic interview conducted on June 9, 2005. The undersigned and the Examiner discussed various issues raised in the present office action. In particular, the undersigned clarified the term "an amino acid sequence" recited in rejected claims 27, 28, 30, and 31 as set forth below. The Examiner also raised the concern during the interview that SEQ ID NO:1 of the present invention and prior art sequence Accession No. AAD05303 disclosed by WO200134626 may represent the same gene based on the alleged 99.7% identity between the two sequences. This concern is addressed below in connection with the corresponding anticipation rejection raised in the office action.

In the office action, the Examiner rejected claims 11-13, 19-21, and 27-31 as indefinite and as anticipated by Tang et al., WO200134626, or GenBank Accession No. BC012074. The Examiner further rejected claims 27-31 as anticipated by St. Croix et al. Each rejection raised by the Examiner is addressed separately below.

Claim 27 is amended to cover only a polypeptide comprising SEQ ID NO:2 by deleting the subject matter of polypeptides that comprise the amino acids 27-321 or 28-320 of SEQ ID NO:2. New claims 32 and 33 are added to cover soluble polypeptides comprising the amino acids 27-321 or 28-320 of SEQ ID NO:2. Support for new claims 32 and 33 can be found at paragraphs [00027] and [00035] of the application. Dependent claims 12, 13, and 19 are amended and new dependent claims 34-36 are added in accordance to the addition of new claims 32 and 33. As a result of the amendments, claims 11-13, 19-21, and 27-36 are now pending in the application.

The addition of new claims does not raise new issues. The subject matter of new independent claim 32 has been previously considered by the Examiner in connection with canceled claim 6 vis a vis the exact same references cited in the present office action. The present response only clarifies a particular claim term and distinguishes the pending claims from the prior art references that have been cited previously. Therefore, the amendments and remarks presented here are believed to be appropriate for entry and consideration in after final practice. Reconsideration of the merits of this application is respectfully requested.

Indefiniteness Rejection

The Examiner rejected claims 11-13, 19-21, and 27-31 alleging that it is not clear whether the term "an amino acid sequence" recited in claims 27, 28, 30, and 31 refers to the

entire sequence of each of the individual sequences listed in the Markush group (SEQ ID NO:2 and amino acids 27-321, 28-320, 41-227, 42-222, and 44-216 of SEQ ID NO:2) or a fragment/portion thereof. In this regard, the Examiner requested clarification from the applicants. The applicants herein clarify that the term “an amino acid sequence” recited in claims 27, 28, 30, and 31 and new claims 32 and 33 refers not to fragments of the indicated sequences but to the entire sequence of each polypeptide listed in the Markush group, i.e., the entire sequence of SEQ ID NO:2 and the entire sequence of amino acids 27-321, 28-320, 41-227, 42-222, or 44-216 of SEQ ID NO:2.

Anticipation Rejection based on Tang et al.

The Examiner rejected claims 11-13, 19-21, and 27-31 as being anticipated by Tang et al. In making the rejection, the Examiner interpreted the claim term “an amino acid sequence” to include fragments of the amino acid sequences listed in the Markush group of claims 27, 28, 30, and 31 (SEQ ID NO:2 and amino acids 27-321, 28-320, 41-227, 42-222, and 44-216 of SEQ ID NO:2). Consequently, the Examiner concluded that the claims are anticipated even though the sequences of Tang et al. do not anticipate the entire sequence of SEQ ID NO:2 or the entire sequence of amino acids 27-321, 28-320, 41-227, 42-222, or 44-216 of SEQ ID NO:2. In view of the clarification made above in connection with the indefiniteness rejection, the applicants believe that the anticipation rejection based on Tang et al. is overcome.

Anticipation Rejection based on WO200134626 (Accession No. AAD05303)

The Examiner rejected claims 11-13, 19-21, and 27-31 as being anticipated by WO200134626 (Accession No. AAD05303). In making the rejection, the Examiner alleged that WO200134626 discloses a polynucleotide sequence (Accession No. AAD05303) that has 99.7% similarity/identity to SEQ ID NO:1 of the present invention. This is not accurate. As discussed in detail below, the 99.7% similarity/identity referred to by the Examiner is for the best local similarity over only a portion of AAD05303 and SEQ ID NO:1.

The polynucleotide sequence of AAD05303 is presented as SEQ ID NO:14 in WO200134626. It contains 2447 nucleotides of which, nucleotides 140-1348 encode a polypeptide of 403 amino acids. SEQ ID NO:1 of the present invention contains 1414 nucleotides of which, nucleotides 104-1207 encode a polypeptide of 368 amino acids. As cited and compared by the Examiner in the office action mailed September 5, 2002,

nucleotides 37-1236 of AAD05303 are 99.7% identical to nucleotides 1-1200 of SEQ ID NO:1 of the present invention. Outside this highly homologous region, however, AAD05303 and SEQ ID NO:1 differ substantially. Notably, the substantial difference extends to part of the coding region. As a result, the polypeptide (SEQ ID NO:2) encoded by SEQ ID NO:1 of the present invention differs from the polypeptide (SEQ ID NO:94 of WO200134626) encoded by AAD05303/SEQ IDNO:14 at amino acid 364 and beyond. These amino acid differences are significant in that they are not merely conservative substitutions (compare Glu Asn Lys Ile Lys of amino acids 364-368 of SEQ ID NO:2 of the present application with Val Ser Asp His Ser of amino acids 364-368 of SEQ ID NO:94 of WO200134626). Therefore, WO200134626 (AAD05303) cannot anticipate amended claims 27 and 28 and their dependents (claims 11-13, 19-21, and 29 and new claims 34-36) with respect to SEQ ID NO:2. It is specifically noted that dependent claim 29 is not anticipated because coding nucleotides 1193-1207 of SEQ ID NO:1 of the present invention differ from the corresponding part of AAD05303 by 60% (9 out of 15 nucleotides are different) leading to completely different coded amino acids.

In addition, WO200134626 (AAD05303) cannot anticipate amended claims 28 and 30 and their dependents (claims 12, 13, 19-21, and 31 and new claims 34-36) with respect to the amino acids 27-321, 28-320, 41-227, 42-222, and 44-216 of SEQ ID NO:2. The disclosure of fragments of proteins in WO200134626 are not limited in any way and thus includes all possible fragments of the proteins such as those of SEQ ID NO:94 (see e.g., page 3, line 25 and claims 1(b), 3, and 4). Such a broad disclosure of all possible fragments cannot anticipate the particular fragments of SEQ ID NO:2 recited in amended claims 28 and 30 and their dependents.

New claim 32 is directed at a soluble polypeptide that comprises the amino acids 27-321 or 28-320 of SEQ ID NO:2. As has already been argued successfully in the response of April 2, 2004 (indicated by the office action mailed October 6, 2004 in which the anticipation rejection based on WO200134626 was withdrawn), such soluble polypeptides are novel over the insoluble full length protein (containing a hydrophobic transmembrane domain) encoded by ADD05303 as well as the general broad disclosure of all possible fragments of the full length protein. Accordingly, WO200134626 does not anticipate new claim 32 and its dependents (claims 12, 13, and 19-21, and new claims 33-36).

Anticipation Rejection based on Accession No. BC012074

The Examiner rejected claims 11-13, 19-21, and 27-31 as being anticipated by Accession No. BC012074. The applicants respectfully traverse the rejection.

The polynucleotide sequence of BC012074 contains 2112 nucleotides of which, nucleotides 113-1114 encode a polypeptide of 334 amino acids. SEQ ID NO:1 of the present invention contains 1414 nucleotides of which, nucleotides 104-1207 encode a polypeptide of 368 amino acids. While nucleotides 10-1063 of BC012074 are highly homologous to nucleotides 1-1054 of SEQ ID NO:1 (differ by only one nucleotide at position 931 of SEQ ID NO:1), they differ substantially elsewhere, including part of the coding region (see sequence alignment between BC012074 and SEQ ID NO:1 submitted with the response filed April 2, 2004). As a result, the polypeptide encoded by SEQ ID NO:1 of the present invention (SEQ ID NO:2) differs from the polypeptide encoded by BC012074 at amino acid 318 and beyond. Therefore, BC012074 cannot anticipate amended claims 27 and 28, new claim 32, and their dependents (claims 11-13, 19-21, and 29 and new claims 33-36) with respect to SEQ ID NO:2 and the amino acids 27-321 and 28-320 of SEQ ID NO:2.

In addition, BC012074 cannot anticipate amended claims 28 and 30 and their dependents (claims 12, 13, 19-21, and 31 and new claims 34-36) with respect to the amino acids 27-321, 28-320, 41-227, 42-222, and 44-216 of SEQ ID NO:2 because BC012074 does not disclose any fragment of the encoded polypeptide, much less the specific fragments recited in the claims.

Anticipation Rejection based on St. Croix et al.

The Examiner rejected claims 27-31 as being anticipated by St. Croix et al. (2000). The applicants respectfully traverse the rejection.

St. Croix et al. disclose a DNA sequence (AF279145) that contains 5540 nucleotides of which, nucleotides 144-1835 encode a polypeptide of 564 amino acids. SEQ ID NO:1 of the present invention contains 1414 nucleotides of which, nucleotides 104-1207 encodes a polypeptide of 368 amino acids. While nucleotides 41-1235 of AF279145 are highly homologous to nucleotides 1-1195 of SEQ ID NO:1 of the present invention (differ by only one nucleotide at position 931 of SEQ ID NO:1), they differ substantially elsewhere, including part of the coding region (see the sequence alignment between AF279145 and SEQ ID NO:1 submitted with the response of April 2, 2004). As a result, the polypeptide encoded by SEQ ID NO:1 of the present invention (SEQ ID NO:2) differs from the polypeptide

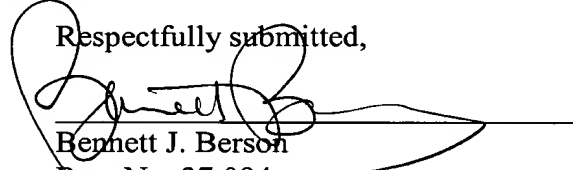
encoded by AF279145 at amino acid 365 and beyond. These amino acid differences are significant in that they are not merely conservative substitutions (compare Asn Lys Ile Lys of amino acids 365-368 of SEQ ID NO:2 of the present invention with Glu Asp Asp Asp of amino acids 365-368 of the polypeptide encoded by AF279145). Therefore, St. Croix et al. (AF279145) cannot anticipate amended claims 27 and 28 and their dependents (claims 11-13, 19-21, and 29 and new claims 34-36) with respect to SEQ ID NO:2. It is specifically noted that dependent claim 29 is not anticipated because coding nucleotides 1196-1207 of SEQ ID NO:1 of the present invention differ from the corresponding part of AF279145 by 75% (9 out of 12 nucleotides are different) leading to completely different coded amino acids.

In addition, St. Croix et al. cannot anticipate amended claims 28 and 30 and their dependents (claims 12, 13, 19-21, and 31 and new claims 34-36) with respect to the amino acids 27-321, 28-320, 41-227, 42-222, and 44-216 of SEQ ID NO:2 as St. Croix et al. did not disclose the above fragments of SEQ ID NO:2 in particular.

New claim 32 is directed at a soluble polypeptide that comprises the amino acids 27-321 or 28-320 of SEQ ID NO:2. As has already been argued successfully in the response of April 2, 2004 (indicated by the office action mailed October 6, 2004 in which the anticipation rejection based on St. Croix et al. was withdrawn), such soluble polypeptides are novel over the insoluble full length protein (containing a hydrophobic transmembrane domain) encoded by AF279145. Accordingly, St. Croix et al. cannot anticipate new claim 32 and its dependents (claims 12, 13, and 19-21, and new claims 33-36).

No extension of time is believed to be necessary and no fee is believed to be due in connection with this response. However, if any extension of time is required in this or any subsequent response, please consider this to be a petition for the appropriate extension and a request to charge the petition fee to the Deposit Account No. 17-0055. No other fee is believed to be due in connection with this response. However, if any fee is due in this or any subsequent response, please charge the fee to the same Deposit Account No. 17-0055.

Respectfully submitted,



Bennett J. Berson

Reg. No. 37,094

Attorney for Applicant

QUARLES & BRADY LLP

P.O. Box 2113

Madison, WI 53701-2113

TEL: 608.251.5000
FAX: 608.251.9166